

---

# Standards in Research

---

## *APA's Mechanism for Monitoring the Challenges*

---

Thomas Grisso  
Elizabeth Baldwin

University of Massachusetts  
Science Directorate, American Psychological  
Association

Peter David Blanck  
Mary Jane Rotheram-Borus  
Nina R. Schooler  
Travis Thompson

University of Iowa  
Columbia University  
University of Pittsburgh  
University of Minnesota

*The original purposes of the American Psychological Association's (APA's) Committee for the Protection of Human Participants in Research (CPHPR), the new purposes of the CPHPR under its new name, the Committee on Standards in Research (CSR) and the scientific and social zeitgeist that has occasioned this change are described. Also several areas of concern about research ethics that are of special interest to the current members of the CSR are identified, and communications between the CSR and APA members on these issues are encouraged.*

In 1978, the American Psychological Association (APA) established the Committee for the Protection of Human Participants in Research (CPHPR), a committee of the Board of Scientific Affairs (BSA). Its main purpose—among other purposes described later in this article—has been to advise the BSA and APA on issues and standards related to the protection of human participants in psychological research. In recent years, however, the range of scientific ethical concerns that the CPHPR has been asked to address has broadened considerably. Therefore, in 1990, the APA officially expanded the committee's scope and renamed it the Committee on Standards in Research (CSR).

In this article, we describe the original purposes of the CPHPR, the new purposes of the CSR, and the scientific and social zeitgeist that has occasioned this change. Then, we identify several areas of concern about research ethics that are of special interest to the current members of the CSR, and we encourage communications between the CSR and APA members on these issues.

### History and Purposes of the Committee

#### *Mission of the Committee*

The need for a committee to advise the APA on issues related to human participants in psychological research arose during a period in which national attention was focused on those issues. Until the 1960s, researchers faced few regulatory restraints or effective guidelines concerning such matters as informed consent, deception of research

participants, and confidentiality in research endeavors. However, during the 1960s and early 1970s a growing national concern emerged about reliance on the individual investigator's conscience as a guide for protecting the general public, children, patients, prisoners, and others when they were participants in scientific research (Faden & Beauchamp, 1986).

In the courts, *Salgo v. Leland Stanford Jr. University Board of Trustees* (1957) broke more than 40 years of relative judicial silence (dating back to *Schloendorff v. Society of New York Hospitals*, 1914) regarding consent in medical situations. The *Salgo* case provided the first use of the term *informed consent*, and the basic legal definition of the concept as we now know it was fashioned by the courts in a line of cases from *Salgo* to *Canterbury v. Spence* (1972). As this doctrine of informed consent developed, it was applied to nonmedical as well as medical research.

Public attention was drawn to the potential for abuse of human research participants in notorious instances such as the Jewish Chronic Disease Hospital case (*Hyman v. Jewish Chronic Disease Hospital*, 1965) and the 1960's Willowbrook case (summarized by Faden & Beauchamp, 1986). In the social and behavioral sciences, several widely publicized studies (e.g., Humphreys, 1970; Milgram, 1974; Zimbardo, Haney, Banks, & Jaffe, 1973) were the centerpieces for vigorous debate about the use of deception of human participants in research.

Many organizations responded to the perceived need for clearer definitions of ethical conduct in human research. For example, the World Medical Association (1977) developed and adopted its "Declaration of Helsinki" in 1964. In the late 1960s, the APA formed an ad hoc Committee on Ethical Standards in Psychological

---

Thomas Grisso was chairman of the Committee for Protection of Human Participants in Research during its transition (1989–1990) to the Committee on Standards in Research (CSR); Peter David Blanck is the 1991 CSR chairman. The other five authors, who include committee members and the committee's APA staff liaison, Elizabeth Baldwin, contributed equally to this article and are listed in alphabetical order.

Correspondence concerning this article should be addressed to Thomas Grisso, Department of Psychiatry, University of Massachusetts Medical Center, 55 Lake Avenue North, Worcester, MA 01655.

Research, which produced the Association's *Ethical Principles in the Conduct of Research With Human Participants* (APA, 1973). Also, new federal definitions and regulations for human research performed with grants from federal agencies were written during the 1960s. Institutional review boards were established (Frankel, 1975), and the *Institutional Guide to DHEW Policy on Protection of Human Subjects* was published (U.S. Public Health Service [USPHS], 1971).

In 1974, Congress convened the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. During the national commission's term, the APA established a task force on ethical issues in human research. This task force became the CPHPR in 1978, the national commission's final year.

The CPHPR has always operated as an advisory and information-providing committee, not a standards-setting or sanctioning body. It has had four general functions: (a) to review proposed policies, (b) to be an informal point of inquiry for researchers, (c) to identify and analyze important, emerging ethical issues, and (d) to disseminate information that will clarify standards and ethical obligations of research psychologists.

**Policy review.** The APA and BSA are often involved in standard-setting activities related to the protection of human participants in research. Some of these activities are internal to the Association. For example, the APA has been revising the *Ethical Principles of Psychologists* (APA, 1981), which in part provides standards for the conduct of research with human participants. In addition, the APA is heavily involved in the review and recommendation of public policy, especially proposed changes and additions to regulations for federally funded research. For example, in recent years, diagnostic tests and clinical field trials with victims of AIDS (acquired immunodeficiency syndrome)-related illnesses have raised a host of difficult ethical issues regarding informed consent, confidentiality, disclosure of results to participants, and random assignment of participants to experimental and placebo medication conditions.

As questions regarding the Association's standards or general public policy have arisen, the APA and BSA have routinely referred them to the CPHPR for study. Through the BSA, the CPHPR has communicated its analyses of the issues and has recommended modifications in draft standards or in positions that the APA should take with regard to proposals for public policy.

**Information resource for researchers.** Researchers often encounter dilemmas in dealing with or interpreting ethical requirements in the conduct of their research with human participants. One method of response when a researcher has telephoned the APA for consultation has been to refer the caller to the Science Directorate's research ethics officer, who is also the BSA's liaison with CPHPR. Either collectively or as individual members, the CPHPR has often served as a resource for information that the research ethics officer can then forward to the inquiring researcher.

The committee's informal responses to these inqui-

ries are in no way adjudicative of ethical disputes, and they do not represent official interpretations of standards by the APA. They are intended only to assist researchers in understanding the issues with which they are dealing and to direct them to other informational and interpretive resources that may clarify their ethical responsibilities.

#### *Identification and analysis of critical ethical issues.*

The CPHPR often has become aware of ethical problems in human subjects research that are not specific to a given case (i.e., they have implications for researchers generally) and that have not been widely recognized or fully conceptualized previously. At times these issues have arisen because of unique challenges presented by new areas of research. At other times they have been in areas that simply had not been given adequate attention.

The less explored ethical questions sometimes have arisen from the interests of the CPHPR members themselves as individual researchers, but they have also tended to surface through the CPHPR's reflection on requests that it receives from other researchers for information about a particular type of ethical dilemma. When such issues are judged to be important for research psychologists in general, CPHPR has often undertaken an in-depth study of those issues. For example, in recent years the CPHPR performed an analysis of the ethical and questionable uses of "subject pools," that is, rosters of undergraduate psychology students from which graduate students and faculty may draw research volunteers.

**Dissemination of information.** The CPHPR has produced and disseminated information that will assist research psychologists by clarifying their ethical responsibilities to research participants and by helping them to develop research procedures that would meet those obligations. For example, members of the committee have written CPHPR-sponsored articles for the *American Psychologist*, reporting the committee's investigation of universities' uses of subject pools (Sieber & Saks, 1989), issues in socially sensitive research involving human participants (Melton, Levine, Koocher, Rosenthal, & Thompson, 1988), and a call for empirical research on research ethics (Stanley, Sieber, & Melton, 1987). The CPHPR also disseminated this type of information in symposia at the APA conventions, and currently it is preparing an "ethics casebook" for use by research psychologists and their students.

#### *The Committee Changes Its Name*

In recent years, the CPHPR became aware that it had been receiving inquiries—from psychologists as well as from the APA—that covered a far broader range of ethical issues than its title identified. Many of these requests reflected an awakened public attention to issues in the conduct of scientific research in general, and to psychological research specifically.

For example, public attention in the 1980s to notorious cases of fraudulent practices in data management and reporting of scientific results gave rise to the U.S. Public Health Service's establishment of the Office of Scientific Integrity and the Office of Scientific Integrity Re-

view (see the Scientific Misconduct section later in this article). These offices were charged with promoting responsible conduct and investigating misconduct in the performance of federally funded research. Cases arose involving conflicts of interest among research scientists, especially questionable uses of public funds for commercially productive research projects (see the Financial Conflict of Interest section later in this article). U.S. congressional attention resulted in draft regulations that would require scientists to report their financial interests prior to receipt of public grant funds.

As these issues came to the attention of the APA, the CPHPR was asked to review them and to advise the Association on appropriate reactions, even though the issues often did not have a direct bearing on human participants in research. Other broader issues of research ethics received by the CPHPR in recent years have focused on psychology's own standards, rather than on federal regulations. For example, the CPHPR has begun a liaison with the APA's publications office in relation to the work of its task force on ethics in publication, and APA has sought CPHPR's input regarding the Association's process for preparing amicus briefs.

In addition, information requests from individual psychologists have covered an increasingly wide range of ethical issues. Requests have included questions about data sharing and data ownership, authorship, database integrity and reliability, data documentation, risk-benefit analyses for proposed studies, and researcher responsibility for the uses of research data.

All of these issues go well beyond the boundaries of ethical concern regarding human participants in research, which was the original purpose of the CPHPR. In one sense, of course, all ethical obligations in research are obligations to research participants. Failure of ethical integrity at any stage of research demeans the participants' contributions. Moreover, public knowledge of unethical research practices, even those that do not directly affect participants (e.g., research fraud), may influence the public's perceptions of the value of their potential involvement when deciding whether to volunteer for future studies. The original mission of the CPHPR, however, was to focus primarily on those matters of research ethics that affected human participants more or less directly.

The CPHPR has not rejected these recent requests for consultation on the broader range of issues of ethical conduct in research. Moreover, the requests themselves seemed to suggest that the APA was in need of a standing committee that would serve the roles that the CPHPR has been playing in the past, but with attention to issues of research ethics generally, not confined to issues of human participants.

Therefore, in 1990, the BSA changed the title and scope of the committee. It is now called the Committee on Standards in Research, and its purview officially includes the wide range of ethical issues in research reflected in the requests of recent years.

In other ways, however, the committee's functions will remain the same. It continues to be a nonadjudicative,

nonsanctioning committee. Its four general functions, noted earlier (policy review, informational resource, analysis of critical issues, and dissemination), will continue. Ethical concerns regarding human participants will still be reviewed by the committee. The change has not influenced the type of work that the committee will do nor identified any waning need for refinement in protections for human research participants. It simply acknowledges the committee's evolution as it has been asked to expand the content of ethical concerns in research that it addresses.

## Future Challenges for Standards in Research

As a part of the process of broadening its focus, the CSR has been identifying topics in research ethics that it believes are especially in need of study. Some of those areas are described in the remaining sections of this article. They are not intended to exclude other important topics (such as research fraud or continuing issues in informed consent and confidentiality) that are being studied actively by the CSR. They merely identify a selection of special interests that the CSR members and APA staff liaison wish to raise to the scientific community of psychologists for future discussion and more intensive study.

### *Publishing Research*

The *Publication Manual of the American Psychological Association* (3rd edition; APA, 1983) and the *Ethical Principles of Psychologists* (APA, 1981) typically serve as the guidelines for psychologists in making ethical judgments regarding how, when, where, what, and with whom to publish. Interpretation and application of these guidelines, however, have been made difficult by the expanding role of government in psychological research and rapid advancements in science and technology. It has been necessary to form special committees (e.g., the USPHS's Office of Scientific Integrity Review) to deal with increasingly complex questions concerning, for example, data ownership, authorship, the responsibility for sharing data, balancing the rights of academic freedom versus the need for informed supervision, and determining the timing and method for releasing "sensitive" results to the public.

One set of ethical questions in publication with which the CSR is especially concerned involves multiple publications derived from the same data set. For example, researchers have asked us the following questions: Is it unethical to publish six articles from one large study? Is it the responsibility of the editor or the researchers to decide when preliminary or partial results should be published? When is it appropriate to release similar results of a study in several different professional publications? If a researcher writes an article for the popular press, is this different from simultaneously publishing in two different types of professional journals?

The concern is with two related issues. One is *partial publication* (sometimes identified by the more colorful term *salami science*). This refers to the dissemination of research results in the "least publishable unit," rather

than publishing results as a coherent whole (Ross, 1984). The second issue is the practice of publishing the same data and results in more than one publishing source, which we will call *dual publication*.

The APA *Publication Manual* states, "Piecemeal [partial] publication of several reports of the results from a single data base is undesirable and may be judged as duplicate publication" (APA, 1983, p. 168). If several articles are to be generated from the same data set, then ordinarily all of the articles are to be submitted to the editor simultaneously, and editors should be informed of any departure from this practice.

These guidelines often are not followed, and it is difficult to monitor the practice, particularly because articles from a single study might be submitted to two or three APA journals and an additional number of non-APA peer-reviewed journals. The impact of partial publication is immediately obvious, however, to investigators who attempt to examine the literature in a research area with which they are not yet familiar. For example, when the same author publishes two reports involving epidemiological surveys of sexual behavior, it may be difficult to determine whether one article reports the results of a preliminary study and the other an enlarged sample with the results of the earlier study nested within it, or whether these are two different samples with replicated findings that provide convincing evidence of a pattern of results. Articles often do not provide sufficient information to allow readers to draw correct conclusions about such matters. The result of partial publication, multiplied over many articles within a topic area, is a lack of integration of research findings that can be bewildering to individuals trying to review accumulated findings within an area (Ross, 1984).

Many realities promote partial publication. For example, editorial policies are sometimes a contributing factor. Journals typically have policies that set extreme limits on the number of words or manuscript pages for articles. It is often impossible to present complex findings involving interdisciplinary research teams and multiple sites in this space. In addition, editors consistently indicate that readers can only digest one or two major points in an article. There are only a few monograph series (e.g., *Monographs of the Society for Research in Child Development*), and books and book chapters are typically undervalued and are not necessarily peer reviewed. Therefore, conditions tend to promote publication of different parts of larger data sets in different articles.

Partial publication typically offers several gains for authors. Publication is the basic criterion for academic tenure and promotion, so researchers feel that they must publish as many articles as possible. Promotion review panels often are composed of academics from a number of different disciplines, making it difficult for all of them to review the actual quality of the researcher's work in his or her specific area. This increases the likelihood that the mere number of publications may achieve greater importance.

Arguments for partial publication sometimes appeal

to the need to address different audiences (Babbie, 1973; Bogdan & Taylor, 1975; Schatzman & Strauss, 1973; Selitz, Wrightsman, & Cook, 1976). Books, journal articles, research notes, and articles in the popular press all serve different functions. One data set may be used for many purposes: to explore a topic of interest, to describe a phenomenon, to explain a concept, or to prescribe action (Babbie, 1973). The level of abstraction, type of background information provided, and technical language will shift dramatically depending on the authors' specific goals in each article. In conceptualizing different audiences, authors may analyze data in different ways and find new results or draw different conclusions (Schatzman & Strauss, 1973).

The need to address different audiences also serves as one of the primary reasons that support dual publication of similar findings. The APA *Publication Manual* (APA, 1983) prohibits dual publication and requires that authors inform editors of simultaneous submission or prior publication of any substantial portion of an article. Moreover, information is not to be released to the press until it has first been published in professional journals. This practice has been challenged, particularly as society is faced with public health crises such as AIDS. For example, controversy recently arose when Secretary of the Department of Health and Human Services (DHHS) Louis Sullivan released results of the AZT (azidothymidine) trials prior to their publication in *The New England Journal of Medicine* and when Robert Gallo announced his discoveries of the retrovirus that causes AIDS (Roberts, 1990).

The APA Ethics Committee has not recorded many violations of partial or dual publication rules (Ethics Committee of the APA, 1988). It may be that these practices are so common that researchers have not realized that they are violations. Alternatively, researchers may recognize that the practices are considered violations but may not themselves believe that the practices are unethical or improper. Nevertheless, it seems clear that researchers have an obligation to warn others (e.g., editors, readers) when a proposed article is part of the author's writing project involving partial or dual publication.

The APA Publications and Communications Board recently formed a special Task Force on Publications to consider issues such as these. The CSR plans to offer assistance to the task force, as needed, and to continue to study the incidence, motivations, and effects of partial and dual publication practices.

### *Uses and Archiving of Videotaped Data*

Videotaped data provide an accurate and complete record of human behavior, minimize selective bias and memory limitations, and permit a permanent record that can be checked for other research purposes and by other researchers (Blanck, 1987). Researchers studying courtroom behavior (e.g., Blanck, Rosenthal, & Cordell, 1985; Blanck, Rosenthal, Hart, & Bernieri, 1990) or family or mental health interactions use videotaped data increasingly often to preserve and analyze human interactions.

There are several compelling reasons for research psychologists to proceed with extreme caution when using videotaped data. Foremost among these are the risks to the protection of the participants' right to privacy and confidentiality. Unlike almost any other data collection technique, participants provide behavioral information through videotaped data that ordinarily would not be permanently recorded. For this reason, the ethical principle of complete informed consent must be accorded special attention.

This is particularly important in research on courtroom behavior. In the context of a criminal trial, for example, researchers must be keenly sensitive to the rights of defendants who have consented to have portions of their trials videotaped for research purposes (Blanck, 1987). In courtroom videotaped research, when one is obtaining complete informed consent from all of the participants (judge, jurors, counsel, and the parties), it is extremely important that they understand how their videotaped data will and could be put to use by the researchers or by the participants themselves in subsequent legal proceedings (Blanck, 1987). For example, defendants must understand fully and consent freely to the conditions under which their particular videotaped data (as opposed to the data of other participants or of other trials in the study) may be used in actions claiming judicial unfairness at the trial (e.g., as manifested in judges' purely nonverbal behavior captured on the videotape).

The transfer of videotaped data from one researcher to another for purposes of secondary analyses also needs to be carefully regulated and governed by guidelines describing who may view the tapes and under what conditions. Questions such as the following may arise: Should participants be required to provide consent each time a new secondary analysis of the tapes is undertaken? Should participants be afforded the opportunity to review their videotaped data before it is placed in an archive? With regard to longitudinal data collection, at what point do children, rather than a parent or guardian, retain their right to consent to the continued use of videotaped data?

One forward-looking attempt to address many of these questions has been undertaken by the Henry Murray Research Center of Radcliffe College. The Murray Center has begun to develop "guiding principles" for the national sharing (via an archive) and transfer of videotaped data for purposes of secondary analyses. The guiding principles also address issues such as the methods for (a) strengthening researchers' capacities to take advantage of video-archiving opportunities, particularly for large data sets, (b) assessing the feasibility of developing an integrated collection of video data, and (c) increasing the portability and reducing the costs of using video data. Efforts such as this will help ensure that videotaped data can be fruitfully and ethically used in research in the future.

### **Research With Vulnerable Populations**

**Poverty.** Of the problems facing the United States, none is more pressing than the plight of disenfranchised people

entangled in the web of poverty. Escalating unemployment, illiteracy, crime, drug abuse, and family violence, with their associated sequelae, have led to proliferating research in an effort to solve these challenging problems. We anticipate burgeoning research over the next decade in these areas. Although greater attention to problems associated with poverty has been long overdue, special ethical issues arise when investigators embark on research to better understand and resolve some of these difficult issues.

Members of racial and ethnic minority groups understandably are wary of research comparing characteristics of their communities with those of members of White middle-class society. Historically, such comparisons have often yielded misleading results, suggesting that problems associated with minority communities exist *because* the community is composed of African Americans or Native Americans, rather than that problems exist because of malnutrition, lack of education, or the disadvantage of being born with fetal alcohol syndrome.

Another problem encountered is the differential effect of research procedures on the lives of people in poverty. In the context of their daily suffering, adding to their distress by using unnecessarily intrusive measures or procedures may be perceived as degrading, adding insult to injury. Transportation may be taken for granted by most people, but asking research participants living at subsistence level to report to a laboratory or clinic across the city or in a nearby town for testing may represent an intolerable burden.

It is important to develop sensitivity to these special ethical concerns regarding potential research participants who live in poverty. Especially needed, for example, are strategies for engaging members of the affected communities in the development of their own research plan (see, e.g., Melton et al., 1988). In addition, professionals working in minority communities may assist the researcher in avoiding the use of tests, instruments, or procedures with inappropriate norms or unexpected effects on the anticipated participants. Basically, however, there has been too little guidance for researchers to alert them to ethical issues in research with persons in poverty—a matter that is of concern to the CSR.

**Vulnerable people in transition.** Special ethical issues are raised by research on the movement of vulnerable people (e.g., people with profound mental retardation or serious mental illness) from large institutional settings to community-based settings. For example:

1. What legitimate role do parents or guardians of vulnerable persons have in the consent process in particular, and in the research endeavor in general?
2. What exactly constitutes valid informed consent to research participation in such studies, when many people with profound mental retardation or serious illnesses are unable to provide traditional forms of written consent?
3. What techniques must be used to assure participants' privacy rights once they reside in the community?
4. What are the responsibilities of researchers in re-

porting their results (either individually or in the aggregate) in a way that protects research participants, families, and the communities in which the participants reside?

Many of these issues are addressed by comprehensive federal, state, and institutional research guidelines (Rozovsky, 1990). Nevertheless, given the particularly sensitive nature of the study of deinstitutionalization, researchers may wish to consider using a "bill of research rights" (Blanck & Turner, 1987) to provide explicit information to participants and families in such studies. This approach helps to identify potentially difficult issues beforehand, such as the type or form of confidential data and information that the researcher may, in certain circumstances, be obligated (ethically or legally) to provide to a state agency or to a court charged with monitoring the quality of community service programs.

An enhanced dialogue on these issues seems particularly warranted in light of the passage of the Americans With Disabilities Act (ADA; Public Law 101-336, 1990). The ADA is a comprehensive civil rights law that is designed to prohibit discrimination in everyday life against individuals with disabilities: for example, in employment, public services and accommodations, and transportation. Ethical and legal issues related to research on the long-term effectiveness of deinstitutionalization will surely emerge in the coming decade.

### **Scientific Misconduct**

The National Science Foundation (NSF) and the USPHS recently established policies and procedures for the review of scientific misconduct. This is especially important for psychologists in research, because these two agencies account for much of the sponsored research conducted by psychologists.

Moreover, these federal agencies serve as models for the establishment of policies by other funding agencies, and compliance with these agencies' requirements influence the policies and practices of universities and private research organizations. Just as the Office for Protection from Research Risks (OPRR) at the National Institutes of Health (NIH) has had a strong effect on institutions' systems for protecting human participants in research, so the policies now being developed by the NSF and USPHS for monitoring and investigating scientific misconduct can be expected to influence the policies of research institutions.

In 1989, the USPHS (1989) established two offices "to strengthen its capacity to deal . . . with investigations of misconduct in science, and to develop and support programs aimed at promoting the responsible conduct of science" (p. 3). They are the Office of Scientific Integrity (OSI) and the Office of Scientific Integrity Review (OSIR).

The OSI is part of the Office of the Director at the NIH, as is the OPRR, and has responsibility for "monitoring and investigating situations that involve possible scientific misconduct" (USPHS, 1989, p. 3). The OSI is also responsible for monitoring (a) investigations that are carried out by grantee research institutions and (b) the scientific misconduct policies put into place by grantees.

In contrast, the OSIR is at an administratively higher level, in the Office of the Assistant Secretary for Health. The OSIR provides oversight to the OSI and has an apparently broad policy development role. The precise relationship of the functions of these two offices will undoubtedly become clearer over time. The OSI, however, will probably be the more salient office for the individual researcher who is being investigated or who has knowledge suggesting the need for an investigation.

In 1987, the NSF issued regulations pertaining to misconduct in science and engineering research (*Federal Register*, 1987, p. 24468). The implementation of these regulations is the responsibility of the Office of the Inspector General (formerly the Office of Audit and Oversight), which can perform misconduct investigations and can apply sanctions to grantee institutions if the institution does not handle alleged misconduct cases fairly.

However, the model followed by both the NSF and the USPHS places primary responsibility for both detection and investigation of scientific misconduct on the research institutions themselves. The funding agencies exercise oversight and can step in to investigate if they judge it necessary.

The definition of scientific misconduct that they are offering to the field includes two key elements: (a) "falsification, fabrication or plagiarism in proposing, conducting or reporting research," or (b) "other practices that seriously deviate from those commonly accepted by the scientific community for honestly proposing, reporting or carrying out research" (USPHS, 1989, p. 2). The latter element of the definition is intended to define whether a situation represents a serious deviation on a case-by-case basis.

The USPHS (1989) has issued a document that defines the "Responsibility of PHS Awardee and Applicant Institutions for Dealing With and Reporting Possible Misconduct in Science." According to this document, USPHS applicants and awardees must have in place policies and procedures that will allow them to review, investigate, and report allegations of misconduct in science that may be made regarding any USPHS-sponsored research at the institution. The standards for meeting these responsibilities include timeliness (e.g., an initial inquiry into an allegation must be completed within 60 days), confidentiality (e.g., the policy must protect the privacy of those who make an allegation and the affected individuals), and notification of OSI at a number of critical junctures along the route from inquiry through formal investigation to the imposition of sanctions.

How these rules will be implemented by research institutions may be anticipated by reflecting on the process that occurred in the 1970s when federal rules required the implementation of institutional policies for the protection of human participants. Research institutions' interpretations of those policies varied within the guidelines mandated by the federal policies. Moreover, procedures for the protection of human participants were applicable to a vast number of investigators; therefore, there were rapid feedback and self-correction of proce-



dures that were unworkable or unfair. In contrast, the institutional procedures being established for scientific misconduct can be expected to be invoked infrequently and will entail some elements of confidentiality. Therefore, it is unclear whether a self-correction process for the development of feasible and fair procedures will occur effectively.

In some ways, the individual researcher's relationship to the policies of federal agencies and research institutions described earlier is much like that of the research participant who is protected by the policies regarding research participation. Researchers are the subject of the policies, but they may not be afforded an active role in their interpretation. Research psychologists, however, will have legitimate concerns regarding both the formulation of these policies and their implementation. We identify several questions and concerns that CSR should consider.

1. What form is taken by the institutional policies currently being developed? How do these policies protect the scientist being investigated, the "whistle blower," and other participants in the research endeavor? Are institutional policies relatively uniform, or are there a variety of ways in which institutions are responding to the federal mandate?

2. How well are the policies working? Are the USPHS and NSF correct in their presumption that institutions can do the job with appropriate oversight? Under what circumstances do the federal agency investigators enter the fray, and what are the consequences? What sanctions are being applied in cases in which misconduct has been established?

3. Can we expect to monitor this process in the way we have monitored the protection of humans or animals in research? Does the need for confidentiality to protect those being investigated conflict with the possibility of learning about the effectiveness of the procedures? Are there ways to monitor the process and still protect confidentiality?

4. What is the effect on the researcher who is the object of a scientific misconduct investigation? Does one always need a lawyer? Does being investigated tarnish a career, regardless of the outcome? What is the effect on the whistle-blower? Is that person penalized?

Finally, organizations like the APA need to be concerned that possible public perception of widespread scientific misconduct could influence support for the scientific endeavor. The CSR will need to work with the BSA to ensure that attention to the issue does not have that effect.

### ***Financial Conflict of Interest***

The problem of financial conflict of interest in science originated in the rise of the biotechnology industry and federal policies that encouraged "technology transfer" from the universities and federal laboratories to the private sector. These two concurrent events fostered conditions that placed a large number of researchers in potentially compromising positions that would allow them to reap large, immediate financial rewards based on their research

(Marshall, 1990). Psychologists have been in this position less often than some of their fellow scientists, but they have been equally affected by the new atmosphere of mistrust and the government guidelines and regulations to deal with the perceived problem.

There have been several well-publicized cases of financial conflict of interest involving researchers who made substantial amounts of money on the basis of either their research results or their positions in the laboratories in which the work was done. One of these cases involved development of a drug, TPA (tissue plasminogen activator), as a treatment to dissolve blood clots that form during a heart attack. Several of the researchers who conducted government studies to test its effectiveness and safety owned stock in the company that had produced it (Okie, 1988). More recently, an NIH AIDS researcher, Syed Zaki Salahuddin, was accused of setting up a company that did business with his laboratory; he hid the relationship as he helped the company to win federal contracts (Culliton, 1990).

These cases and others led to congressional hearings on fraud, misconduct, and financial conflict of interest in science. Representatives in Congress did not trust the argument that this was a problem best handled by scientists and that the process of scientific replication of studies would bring to light fraudulent research. They see it as their responsibility to help oversee millions of taxpayer dollars that pay for research; they do not see these circumstances as being different from any other government contract. Several hearings held since 1988 by Representative John Dingell of Michigan, chair of the House Committee on Energy and Commerce, have kept the spotlight on science. Representative Dingell's highly visible investigations of the *Cell* paper co-authored by Nobel laureate David Baltimore (Thompson, 1989), as well as the NIH researcher Salahuddin, noted earlier, put pressure on federal research agencies to promulgate rules and guidelines to control the problem. Representative Ted Weiss of New York, chair of the Subcommittee on Human Resources and Intergovernmental Relations of the House Government Operations Committee, also held hearings that explored the issues of conflict of interest, data ownership, and technology transfer in federal research agencies.

Most scientists were not accustomed to such intense scrutiny, and many regarded the matter as a nonproblem for the majority of researchers. Regardless of researchers' personal opinions as to the frequency and severity of breaches in research ethics, however, it was obvious that some response was necessary. There was a need to deal with congressional concerns and to reassure the public that its investment in research was being well spent and well managed. The NIH and the Alcohol, Drug Abuse, and Mental Health Administration (through the USPHS), as well as the NSF, issued rules and guidelines to require the establishment of administrative procedures at their grantee institutions to deal with fraud and misconduct in their research laboratories. This process was accomplished through the publication of proposed rules and

allowed for public comments before finalization. A similar process is being used to set up an institutional and agency response process for financial conflict of interest in science.

There have been problems, however, with this latest attempt at federal rule making. For example, in previous rule-making exercises, whenever there have been disagreements as to how to define such matters as *fraud* and *misconduct*, most scientists at least have been able to agree that they know it when they see it. What was needed, therefore, were regulations that would protect honest error and scientific disagreements from being construed as fraud and misconduct. This is not the case, however, with financial conflict of interest. The stakes are much higher and the administration and industry must seek a balance between the promotion of technology transfer and the promulgation of regulations that would limit researchers' financial stake in their work (Blum, 1989).

There were several criticisms made after the publication of the "Proposed Guidelines for Policies on Conflict of Interest" in the *NIH Guide for Grants and Contracts* (DHHS, 1989). The most vociferous was that the proposed guidelines would stifle technology transfer that was essential in new industries like biotechnology. The proposed guidelines would have disallowed any financial relationship between federally funded researchers and any company that stood to profit from their research.

In addition, the proposed regulations would require all researchers accepting federal research grants to disclose all of their personal financial investments, as well as those of their family members, prior to receipt of funding. Questions of privacy were raised, especially for the vast majority of federally funded research psychologists whose research is not of a type that produces any prospect for immediate financial gain.

The proposal was withdrawn on December 29, 1989, by DHHS Secretary Sullivan, with the announcement that the guidelines would be "reworked" and published for further comment before becoming final. It is not expected that the final rules on financial conflict of interest will be in place until 1992.

What are the interests of research psychologists in this matter? Psychologists do not find themselves in the same position as many biomedical researchers (who have accounted for the more spectacular cases). Do psychologists need to be concerned about the ethical issues inherent in the national debate? Are there different concerns or expertise that psychologists can bring to the discussion? Are there potential problems that can be discussed now, before they grow?

## Conclusion

We have raised these particular issues not because they are any more pressing than scores of other questions about ethical standards that face research psychologists today, but merely because they represent special interests brought to the CSR by those of us who currently serve on the committee. The study of these issues is likely to

form a part of the committee's agenda in the next few years, but its attention to these matters will in no way be exclusive with regard to any other concerns that arise.

We strongly encourage the community of research scholars in psychology to bring to our attention any other questions regarding ethical standards that they encounter in their work and that they feel are in need of study as a matter of policy. The most direct way to bring questions and issues to the attention of the CSR is to contact the CSR staff liaison within the Science Directorate at the APA.

As noted earlier, the CSR does not adjudicate case-specific questions of ethical conduct by researchers, and it does not function as an arbitrator of matters between co-investigators or between researchers and their institutions. Nevertheless, it is often by hearing about specific ethical conflicts encountered by researchers in their own projects that the committee identifies new questions that are worth studying. In the long run, this helps us to recommend policy formation and policy change, and thereby to refine our standards for research promulgated by the American Psychological Association.

## REFERENCES

- American Psychological Association, Committee for the Protection of Human Participants in Research. (1973). *Ethical principles in the conduct of research with human participants*. Washington, DC: Author.
- American Psychological Association. (1981). Ethical principles of psychologists. *American Psychologist*, 36, 633-638.
- American Psychological Association. (1983). *Publication manual of the American Psychological Association* (3rd ed.). Washington, DC: Author.
- Americans With Disabilities Act, PL 101-336 (1990).
- Babbie, E. (1973). *Survey research methods*. Belmont, CA: Wadsworth.
- Blanck, P. (1987). The process of field research in the courtroom. *Law and Human Behavior*, 11, 337-358.
- Blanck, P., Rosenthal, R., & Cordell, L. (1985). The appearance of justice: Judges' verbal and nonverbal behavior in criminal jury trials. *Stanford Law Review*, 38, 89-164.
- Blanck, P., Rosenthal, R., Hart, A., & Bernieri, F. (1990). The measure of the judge: An empirically-based framework for exploring trial judges' behavior. *Iowa Law Review*, 75, 653-684.
- Blanck, P., & Turner, A. (1987). Gestalt research: Clinical-field research approaches to studying organizations. In J. Lorsch (Ed.), *Handbook of organizational behavior* (pp. 109-125). Englewood Cliffs, NJ: Prentice-Hall.
- Blum, D. (1989, July 5). Stricter conflict rules could stifle campuses: NIH is warned. *Chronicle of Higher Education*, pp. A11-12.
- Bogdan, R., & Taylor, S. (1975). *Introduction to quantitative research methods*. New York: Wiley.
- Canterbury v. Spence, 464 F.2d 772 (D.C. Cir. 1972).
- Culliton, B. (1990). Dingell: AIDS researcher in conflict. *Science*, 248, 676.
- Ethics Committee of the American Psychological Association. (1988). Trends in ethics cases, common pitfalls, and published resources. *American Psychologist*, 43, 564-572.
- Faden, R., & Beauchamp, T. (1986). *A history and theory of informed consent*. New York: Oxford University Press.
- Federal Register. (1987, July 1). pp. 24466-24470.
- Frankel, M. (1975). The development of policy guidelines governing human experimentation in the United States: A case study of public policy-making for science and technology. *Ethics in Science and Medicine*, 2, 43-59.
- Humphreys, L. (1970). *Tearoom trade: Impersonal sex in public places*. Chicago: Aldine.
- Hyman v. Jewish Chronic Disease Hospital, 251 N.Y. 2d 818 (1964), 206 N.E. 2d 338 (1965).



- Marshall, E. (1990). When commerce and academe collide. *Science*, 248, 152-156.
- Melton, G., Levine, R., Koocher, G., Rosenthal, R., & Thompson, W. (1988). Community consultation in socially sensitive research: Lessons from clinical trials of treatments for AIDS. *American Psychologist*, 43, 573-581.
- Milgram, S. (1974). *Obedience to authority*. New York: Harper & Row.
- Okie, S. (1988, September 30). Drug's testers had stock in its maker: Disclosure raises doubts about studies of heart treatment. *The Washington Post*, p. A6.
- Roberts, S. (1990, July). What AIDS researcher Dr. Robert Gallo did in pursuit of the Nobel prize. *Spy*, pp. 70-79.
- Rozovsky, F. (1990). *Consent to treatment: A practical guide*. Boston: Little, Brown.
- Ross, A. (1984). Integrity in the science and profession of clinical psychology. *Clinical Psychologist*, 37, 15-18.
- Salgo v. Leland Stanford Jr. University Board of Trustees, 317 P.2d 170 (1957).
- Schatzman, L., & Strauss, A. (1973). *Field research: Strategies for a natural sociology*. Englewood Cliffs, NJ: Prentice Hall.
- Schloendorff v. Society of New York Hospitals, 211 N.Y. 125, 105 N.E. 92 (1914).
- Sellitz, L., Wrightsman, L., & Cook, S. (1976). *Research methods in social relations (3rd ed.)*. New York: Holt, Rinehart & Winston.
- Sieber, J., & Saks, M. (1989). A census of subject pool characteristics and policies. *American Psychologist*, 44, 1053-1061.
- Stanley, B., Sieber, J., & Melton, G. (1987). Empirical studies of ethical issues in research. *American Psychologist*, 42, 735-741.
- Thompson, L. (1989, May 9). Science under fire: Behind the clash between Congress and Nobel laureate David Baltimore. *The Washington Post Health*, pp. 12-16.
- U.S. Department of Health and Human Services. (1989, September 15). Proposed guidelines for policies on conflict of interest. *NIH Guide for Grants and Contracts*, 18(32), 1-5.
- U.S. Public Health Service (1971, December). *The institutional guide to DHEW policy on protection of human subjects* (DHEW Publication No. NIH 72-102). Washington, DC: Government Printing Office.
- U.S. Public Health Service. (1989, September 1). Responsibilities of awardee and applicant institutions for dealing with and reporting possible misconduct in science [Special Issue]. *NIH Guide for Grants and Contracts*, 18 (30).
- World Medical Organization (1977). Declaration of Helsinki: Recommendations guiding medical doctors in biomedical research involving human subjects. In S. Reiser, A. Dyck, & W. Curran (Eds.), *Ethics in medicine: Historical perspectives and contemporary concerns* (pp. 328-329). Cambridge, MA: MIT Press.
- Zimbardo, P., Haney, C., Banks, W., & Jaffe, D. (1973, April 8). The mind as a formidable jailor: A Pirandellian prison. *The New York Times Magazine*, pp. 38-60.